



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/527,767
Filing Date: September 12, 2005
Appellant(s): BAXENDALE ET AL.

William Blackstone
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 29, 2009 appealing from the Office action mailed August 6, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

Claims 1 and 4-10 are pending.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The amendment after final rejection filed on December 8, 2008 has been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection under 35 U.S.C. 112, first paragraph.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of base claim 1 indicates that these claims are drawn to a genus, i.e. “*or [in the alternative] a CAsIV-2 that is able to induce antiserum having a neutralizing antibody titre greater than or equal to 128 against the deposited virus as measured in a virus neutralization assay and greater than or equal to 32 as measured in an immunofluorescence assay.*”

Although the first three lines of claim 1 recite the deposited virus, which Appellant has demonstrated possession and therefore is allowable, lines 3-6 of claim 1 recites in the alternative a genus of viruses that can produce antibodies to neutralize the deposited virus **or** that can induce cross-reactive antibodies to neutralize the deposited virus. However the specification fails to describe any genus or any other virus species that can be used to produce antibodies to neutralize the deposited virus CAsIV.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the

genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states “[a]n adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.”

A single species of the claimed genus is disclosed that is “*CastV-2 deposited under the accession no. I-2923 at the Collection Nationale de Cultures de Microorganismes of the Institute Pasteur, Paris, France*”. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not described. There reasonably is substantial variability among the species while still maintaining the ability to generate antiserum as claimed. In the absence of sufficient recitation of distinguishing characteristics, particularly which structural features must be conserved to maintain the recited functional characteristic, the specification has not provided adequate written description of the claimed genus, which is a generic “*CastV-2 that is able to induce antiserum*” that neutralizes the deposited virus. One of skill in the art would not recognize from the disclosure that the Appellant was in possession of the genus. The specification does not clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116). Appellant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

In summary, the skilled artisan cannot envision the detailed structure of a genus of compounds that are contemplated in the invention. Conception is not reasonably achieved until reduction to practice has occurred of a representative number of species falling within the genus, regardless of the complexity or simplicity of the structures disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that Appellant was in possession of the claimed invention as presently claimed.

(10) Response to Argument

Appellants argue “Appellants have identified three different specimens of their novel chick astrovirus type 2 subtype and have distinguished them from the known chicken astrovirus ANV (CAst-V-1) and from other avian astroviruses (TastV and DVH-2) in virus neutralization and immunofluorescence assays.” The Board should not be persuaded by this argument because the viruses tested are different viruses and therefore different species. For example, *chicken* astrovirus *type 1* (ANV) is structurally different from the deposited *chicken* astrovirus *type 2* (CAstV-2) (see Table 1a of the specification). *Turkey* astrovirus (TastV) and *duck* astrovirus (DVH-2) are also structurally different from *chicken* astrovirus (CAstV-2) (see Tables 1a and 1b of the specification).

Appellants argue “Appellants have also demonstrated that they had isolated two other isolates of the same chicken astrovirus type 2, which were identified using the same criteria that are included in claim 1 as characterizing limitations.” Appellant’s assertion that two other isolates have been identified is simply incorrect. Appellants have not provided structures or sequences for the two other isolates. Appellants have not provided deposits of these other isolates. Therefore Appellants have not reasonably shown possession of the other two isolates because the specification fails to show any correlation between structure and function with the other putative isolates.

Appellants argue “Appellants showed, in the results presented in Table 2 on page 14 of the specification, that the other viruses of this subtype meet minimum levels of cross neutralization antibody titer and immunofluorescence.” Table 2 discloses CAsV-2 strains: VDU/AS1, VDU/AS2 and VDU/AS3, wherein Example 2 describes the neutralization assays and immunofluorescent test (IFT). Appellants’ disclosure does not describe or provide DNA sequences for these isolates. Therefore the disclosure fails to describe any structure for the chicken astrovirus strains claimed. Table 2 further discloses different functional characteristics for these isolates (i.e. as it relates to different immunofluorescence and neutralization data presented in Table 2 of the specification).

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), “an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself”. *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGFs were found unpatentable due to lack of written description for the

broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single chicken astrovirus species (the deposited CAsV-2 accession no. I-2923) has been described in the instant specification.

Appellants argue

“[t]o demonstrate the unique characteristics of the chicken astrovirus type 2 compared with other avian astroviruses, Appellants provided in Tables 1a and 1b, on pages 12 and 13 of the specification, neutralization and immunofluorescence results. These results compared CAsV-2 AS2 with CAsV-1 ANV and turkey astrovirus TasV (Table 1a), and CAsV-AS1 with CAsV-1 ANV and duck astrovirus DVH-2 (Table 1b). Then, in Table 2, on page 14, the high levels of cross-reactivity for neutralization and immunofluorescence among CAsV-2 isolates AS1, AS2 and AS3 are reported, which were compared with the negligible cross-reactivity results reported for the non type 2 astrovirus isolates in Tables 1a and 1b.”

The Board should not find this argument persuasive because the species discussed above do not represent the genus of viruses that can be used to produce antibodies to neutralize the deposited chicken astrovirus virus type 2 (CAsV-2). Tables 1a and 1b disclose neutralization assays and immunofluorescence assay results of other viruses in the family of astroviruses (i.e. *chicken* astrovirus type 1, *turkey* astrovirus and *duck* astrovirus) but do not provide any structures of these viruses (i.e. *chicken* astrovirus type 1, *turkey* astrovirus and *duck* astrovirus). A person of ordinary skill in the art cannot reasonably visualize what structural, or correlation of functional and structural characteristics, are representative of the genus of CAsV-2 viruses (i.e., type 2) claimed, because description of one species of CAsV-2 (i.e., the deposited CAsV-2 of Accession no. I-2923) does not constitute a genus, by definition, and because the specification

fails to provide any structural characteristics for the claimed genus, only functional characteristics that differ (e.g., see Tables 1a, 1b and 2 in the specification).

It should be noted that even the presence of multiple species within a claimed genus does not necessarily demonstrate possession of the genus. See, *In re Smyth*, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in the performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, at 1405 (Fed Cir 1997) (citing *Smyth* for support). Thus, when a claim covers a genus of inventions, the specification must provide sufficient written description support for the entire scope of the genus. Support for a genus is generally found where the Appellant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed, or provided a function and a structure correlating with that function. However, in situations where the operability of other species than those provided is uncertain, additional support is required over that which would be required where greater certainty is present.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Sharon Hurt/
Examiner, Art Unit 1648

Conferees:

/Robert C. Hayes, Ph.D./
Primary Examiner, Art Unit 1649

/Jeffrey Stucker/
Supervisory Patent Examiner, Art Unit 1649

Gary Nickol Ph.D.

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646